

## **REMARKS**

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

### **Status of the Claims**

Claims 6-16, 18-20, 24-39 have been withdrawn from consideration. This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented, with an appropriate defined status identifier. Upon entry of this amendment, claims 1-5, 17, and 21-23 are currently pending in this application. Claims 1-2 and 4 are currently amended.

### **Election/Restriction**

Claims 38-39, which were newly submitted in the Amendment filed on January 16, 2004, were withdrawn by the Examiner as directed to non-elected subject matter. Applicants reserve the right to pursue the subject matter of claims 38-39 in one or more divisional applications.

### **Rejection of claims 1-5, 7-8, 17, 21-23, and 37 under 35 U.S.C. § 112, second paragraph**

Claims 1-5, 7-8, 17, 21-23, and 37 are rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite. In particular, the Office Action asserts that “it is not clear from the specification or Figures what sequence identifier is associated with Figure 4.” The current form of the claims avoids this rejection. Accordingly, Applicants respectfully request withdrawal of the rejection.

Claim 7 is also rejected under 35 U.S.C. § 112, second paragraph because the recitation, “introducing a point modification or mutation at residue 4, 5, 6, 7 or 8” is allegedly unclear as to “what residues comprise these particular positions.” Claim 7 has been

withdrawn, obviating this rejection. Applicants respectfully request withdrawal of this rejection.

Claims 4-5 and 7 are also rejected under 35 U.S.C. § 112, second paragraph because it is allegedly unclear how the process or method clearly defines the preamble recitation. The present form of the amended claims avoids this rejection. Accordingly, Applicants respectfully request withdrawal of this rejection.

**Rejection of claims 2-5 and 7 under 35 U.S.C. § 112, first paragraph**

Claims 2-5 and 7 remain rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to meet the written description requirement. In particular, the Office Action asserts that the claims “read on an infinite number of variant peptides,” but “the written description in this case only sets forth a recombinant peptide comprising SEQ ID NO:1 and a recombinant peptide consisting of SEQ ID NO: 2.” Office Action at 4: The Office Action further alleges that “the claims do not require that the polypeptide fragment(s) or the methods thereof possess any particular conserved structure, or other disclosed distinguishing feature.” *Id.* The present form of the claims avoids this rejection.

Applicants recognize that this is the first presentation of the claims 2 and 4 in their current form and that claim 7 is newly withdrawn. The evidence and explanation of record do not establish that the current form of claims 2-5 lack written description support in the specification. “[T]o comply with the written description requirement, it is not necessary that the application describe the claimed invention in *ipsis verbis*; all that is required is that it reasonably convey to persons skilled in the art that, as of the filing date thereof, the inventor had possession of the subject matter later claimed by him.” *In re Edwards*, 568 F.2d 1349, 1351-52, 196 U.S.P.Q. 465, 467 (C.C.P.A. 1978) (citations omitted), *see also, Vas-Cath v. Marhurkar*, 935 F.2d 1555, 1564 (Fed. Cir. 1991).

The current form of claims 2-3 complies with the written description requirement. Amended claims 2 and 3 depend from claim 1 and recite that the peptide comprises SEQ ID NO: 2 (claim 2) and that the peptide comprises at least one element other than natural amino acids (claim 3). Both claims 2 and 3 incorporate the limitations of claim 1, namely that the

peptide compound comprises SEQ ID NO: 1 or a fragment thereof, wherein the fragment comprises SEQ ID NO: 2, and wherein the peptide causes a specific T response. The polypeptide compound claimed in the current form of claims 2-3 recites conserved structure, namely that peptide compound comprises SEQ ID NO: 1 or a fragment thereof, wherein the fragment comprises SEQ ID NO: 2. The polypeptide compound of claims 2-3 also recites a distinguishing features, namely that the peptide causes a specific T response. Thus, the claims have sufficient written description support. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

The current form of claims 4-5 also satisfy the written description requirement and thus avoid the instant rejection. Amended claims 4-5 recite both conserved structure and a distinguishing feature. Amended claim 4 is directed to a method for identifying a peptide compound having an anchoring motif for a given HLA molecule comprising:

- a) determining a peptide compound comprising an anchoring motif for a given HLA molecule, wherein the peptide fragment comprises a sequence of approximately 9 to 10 amino acids of SEQ ID NO: 1,
- b) testing the immunogenicity of the peptide compound obtained in step a) by carrying out an Elispot assay, and
- c) identifying the peptide compound, wherein the peptide fragment is reactive in the Elispot assay, and wherein the peptide compound comprises anchoring motif for the given HLA molecule.

Claim 5 is directed to a peptide compound obtained using the method of claim 4. Claims 4-5 clearly recite conserved structure, namely that the peptide compound comprises 9-10 amino acids of SEQ ID NO: 1 and contains an anchoring motif for a given HLA molecule. Claims 4-5 also clearly recite a distinguishing feature, namely that the peptide compound is reactive in the Elispot assay. One of skill in the art, armed with the instant specification, would readily understand what is meant by reactive in an Elispot assay. *See, e.g.,* Specification at page 4, lines 15-36. Thus, claims 4-5 find ample written description support in the specification.

Accordingly, Applicants respectfully request withdrawal of the rejection.

**Rejection of claims 17 and 21-23 under 35 U.S.C. § 112, first paragraph**

Claims 17 and 21-23 remain rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking enablement for the reasons of record. Specifically, the Office Action states that the “claims are drawn to pharmaceutical compositions wherein it is maintained that the teachings of the specification does not provide sufficient guidance and or objective evidence that such pharmaceutical compositions would predictably and effectively function as contemplated.” Applicants respectfully traverse this rejection.

The evidence and explanation of record does not establish that the current form of claims 17 and 21-23 lack enablement. Claims are presumptively enabled. M.P.E.P. § 2164.04. A rejection for lack of enablement must include specific technical reasons why the claims are not enabled. *Id.* Furthermore, all factual findings that are material to patentability must be supported by substantial evidence. *In re Zurko*, 258 F.3d 1379, 1386 (Fed Cir. 2000).

The Office Action rejects the claims for the reasons of record. However, the reasons of record address a previous form of the claims and do not discuss the claims as amended in the Amendment filed on January 26, 2004. The evidence and explanation of record do not establish lack of enablement of the current form of the claims. The reasons of record, namely the reasons recited in the Office Action dated August 25, 2003, assert, “The claims are broadly drawn to peptide compounds of at least 8 consecutive amino acids of SEQ ID NO:1 that cause a specific T cell response.” Office Action at 12. However, in their current form, claims 17 and 21-23 are not directed to a sequence of at least 8 consecutive amino acids, or approximately 9 to 10 amino acids of SEQ ID NO: 1. The current form of the claims are drawn to peptide comprising SEQ ID NO: 1 or a fragment thereof, wherein the fragment comprises SEQ ID NO: 2. Moreover, the claimed compounds cause a specific T response. Thus, a skilled artisan could readily identify a claimed peptide which is suitable for use in the presently claimed pharmaceutical composition and would understand how to use the claimed peptide. There is no evidence and explanation of record establishing lack of enablement of the current form of the claims. Accordingly, Applicants respectfully request withdrawal of the rejection.

### CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16 1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741..

Respectfully submitted,

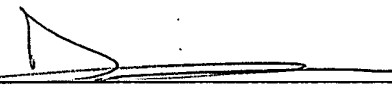
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